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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,568	08/02/2006	Bellamkonda Kishore	21101.0040U2	2536

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,568	KISHORE ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2010*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,15,19-30,32-41,52,56-59,61-67,72-78,81-84,98-101 and 103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5,15,19-30,32-41,52, 56-59,61-67,72-78,81-84,98-101 and 103* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The rejections made in the last Office action are withdrawn in response to the amendment and response file 5/28/2010.

In response to the amendment filed 5/28/2010, the following restriction requirement is set forth.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3, 5 and 103, drawn to a composition comprising erythropoietin (Ep) and an EPIP.

Group II, claim(s) 2, 4, 15 and 19-29, drawn to an EPIP (erythropoietin production producing peptide).

Group III, claim(s) 30 and 32-39, drawn to cells treated with an EPIP.

Group IV, claim(s) 40, drawn to a method of administering Ep to a subject.

Group V, claim(s) 41, 52, 56-59 and 61-67, drawn to a method of administering an EPIP and Ep to a subject.

Group VI, claim(s) 72, drawn to a method for making cells and producing Ep *in vitro*

Group VII, claim(s) 73-78, 81-84 (claims 81-83 are presumed to depend from claim 74 unless Applicant amends otherwise), drawn to a method for method for making cell and producing Ep *in vivo*.

Group VIII, claim(s) 98-102, drawn to a method of making a cell that produces Ep.

(a) An international or national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those invention involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) a product and a process specially adapted for the manufacture of said product; or

(2) a product and a process of use of said product; or

(3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) a process and an apparatus or means specifically designed for carrying out said process; or

(5) a product, a process specially adapted for the manufacture of the said product and an apparatus or means specifically designed for carrying out said process.

The groups of invention I and V fall within category (2), a product and a method of use of that product.

PCT Rule 13.2 does not provide for multiple compositions or multiple methods of use or making within a single application. Thus, the first appearing composition is combined with a corresponding first method of using and the additional composition and method claims each constitute a separate group.

In addition to the requirement that a group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, such as a composition and a method of using of the composition, must have a special technical feature that unites them. See Patent Rules 1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

Using the specification as a dictionary, the specification defines an EPIP as any peptide that directly or indirectly stimulates the proliferation of fibroblasts which in turn produce Ep (p. 18, lines 8-10). Owen et al. (US 2003/0109452) disclose the administration of FLAK peptides to human fibroblasts and the stimulation of the production of the fibroblast cells by the FLAK peptides p. 19, Table 22. Hence, the method of Owen et al.

produces a composition comprising cells containing a peptide that stimulate the production of a fibroblast (an EPIP) which in turn makes Ep. Hence, a composition comprising Ep and an EPIP is disclosed by the prior art and there is no special technical feature that unites Groups I and V.

Similarly WO 01/66149 (Valentis, Inc.; cited in the IDS) teaches compositions comprising poly-L-glutamic acid and a nucleic acid encoding Ep that is delivered to cells to stimulate Ep production (p. 6, lines 21-25). Hence, this method produces a composition comprising cells that have Ep and poly-L-glutamic acid (an EPIP). Hence, a composition comprising Ep and an EPIP is disclosed by the prior art and there is no special technical feature that unites Groups I and V.

The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (PCT Rule 13.2). Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(a) poly-D-glutamic acid, poly-L-glutamic acid, poly-D-glutamic acid, poly-L-aspartic acid or poly-D-aspartic acid;

(b) treatable diseases or conditions recited in claim 56-59;

(c) cells for making Ep from claims 81-83;.

In addition to the election from groups I to VIII above **applicant is also required**, in reply to this action, to elect **a single species from each of (a) through (c) above**, to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also

identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 12, 15, 30, 32, 36, 41, 52, 67 and 75 correspond to specie (a);
Claims 56-59 correspond to specie (b);
Claims 81-83 correspond to specie (c); and

The following claim(s) are generic: 1-5, 19-30, 33-35, 37-41, 56-59, 61-66, 72-74, 76-78, 81-84, 98-101 and 103 are generic for specie (a).

Claims 41, 52, 56 and 61-67 are generic for specie (b) as they relate to Group V.

Claims 73-78 and 84 are generic for specie (c) as they relate to Group VII.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

For the species (a), compositions comprising the named anionic polymers are known supra (WO 01/66149; p. 6, lines 21-26 and p. 43, lines 5-10). As noted, a feature found in the prior art cannot be considered to be a special technical feature.

The diseases recited in claims 56-59 lack a common special technical feature since they have different patient sets etiologies and pathologies.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Irene Marx/
Primary Examiner
Art Unit 1651